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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/291,426	04/13/1999	KEN JAMES	P-22577GUSA	2084

7590 04/02/2003
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EXAMINER

CELSA, BENNETT M

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 04/02/2003

22

Please find below and/or attached an Office communication concerning this application or proceeding.

file copy

Office Action Summary

Application No.

09/291,426

Applicant(s)

James, K.

Examiner

Bennett Celsa

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 and 20-28 is/are pending in the application.
- 4a) Of the above, claim(s) 4, 6-8, 11-13, 15, 16, 22, 25, and 28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 9, 10, 14, 17, 18, 20, 21, 23, 24, 26, and 27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 20 6) ☐ Other:

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/10/03 has been entered.
2. In light of the amended claims and the modification of existing (and the raising of new rejections) in response to these amendments, the Examiner will consider arguments already of record, and any newly raised arguments, in the next office action.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. **NOTE:** the location of the present application is ART UNIT 1639.

Status of the Claims

Claims 1-18 and 20-28 are currently pending.

Claims 4, 6-8, 11-13, 15, 16, 22, 25 and 28 are withdrawn from consideration as being directed to a nonelected invention.

Claims 1-3, 5, 9, 10, 14, 17-18, 20, 21, 23, 24, 26 and 27 are under consideration

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Election/Restriction

5. Applicant's election, without traverse, of Group I (claims 1-27) and species election in paper no. 7 and 10 in response to the restriction/election requirement in paper no. 5 is again acknowledged. In papers no. 7 and 10 applicant elected:

- a. Group I, claims 1-27;
- b. The species of claims 5, 14, 17 and 21;
- c. Elected a compound of the structure depicted in claim 21:

wherein b is 1; R1 is (CH₂)_a, wherein a is 2, in which the R1 linking moiety on the left side of the first monomeric structure is attached to the left side of the benzene ring para to the hydroxy group attached to the aforementioned ring and the (CH₂)_b moiety on the right side of the first monomeric structure is attached to the right side of the benzene ring.

d. The species of claim 19, wherein:

1. The second monomer series is carboxylic acids;
 - [2. The third monomer series is ethylene oxide; embodiment cancelled by applicant]
- e. The species of claim 28, wherein copolymers are further modified by crosslinking.

Withdrawn Objection (s) and/or Rejection (s)

The obviousness rejection over the Kohn '449 reference (in combination) is withdrawn since the issues addressed in this rejection appear to be superfluous to those raised in the Kohn '115 obviousness rejection which has been rewritten as a 102/103 rejection

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Objection(s) and/or Rejection (s)

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-3, 5, 9, 10, 14, 17-18, 20, 21, 23, 24, 26 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. In claims 1 and 10 (and claims dependent thereon), the "number of homologously bivariant copolymers" comprising libraries of strictly alternating A-B type copolymer libraries, the number of which are "sufficient to incrementally establish quantitative structure-property correlations" is indefinite since the amount "sufficient to incrementally establish quantitative structure property correlations is "relative"; variable variable from one type of A-B copolymer to another; and variable dependent upon what quantitative structure property is being evaluated. Additionally, the term "a number... sufficient to incrementally establish quantitative structure-property correlations" in the claims is a relative term which renders the claim indefinite. The term "a number... sufficient to incrementally establish quantitative structure-property correlations" is not defined by the claim, nor does the specification provide a standard for ascertaining the requisite degree necessary to incrementally establish quantitative structure-property correlations, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

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B. In claims 1 and 10 (and claims dependent thereon) the terms "selected to have *comparable* reactivities" and "of *sufficiently high* molecular weight and *similar* polydispersity" claim are relative terms which renders the claim indefinite. These terms are not defined by the claim, nor does the specification provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. .

8. Claims 1-3, 5, 9, 10, 14, 17-18, 20, 21, 23, 24, 26 and 27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention (NEW MATTER REJECTION) .

The Amendment dated January 10, 2003 (paper no. 19) amending claims 1 and claims 10 (and claims dependent thereon) to add limitations addressing homologically bivariant copolymer A-B libraries (e.g. "selected to be complimentary to one another"; "to incrementally establish quantitative structure property correlations; "... all polymers being of sufficiently high molecular weight and similar polydispersity " etc.) constitutes new matter to the extent that the claimed invention is broadly applicable to "copolymer libraries of strictly alternating A-B type copolymers" OTHER THAN those disclose in the specification (e.g. on pages 10-11) which are directed to the making of polyarylates using specific tyrosine derived phenols and diacids.

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9. Claims 1-3, 5, 9, 10, 14, 17-18, 20, 21, 23, 24, 26 and 27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention (LACK OF WRITTEN DESCRIPTION).

In the present case, the claims are drawn to a product-by-process claims wherein the product is drawn to a library of "strictly alternating A-B type copolymers" comprising "a number of homologically bivariant copolymers sufficient to incrementally establish quantitative structure-property correlations" which is formed from parallel polymerization of monomers. The CLAIMED scope of copolymer (e.g. A-B) libraries lacks metes and bounds as to the resulting polymer compound (CORE) structure; since :

-
- a. each of the individual monomers (e.g. A,B) is varied (one or more times) as to monomer "core" structure (e.g. keeping constant the "polymerizable functional groups"),
 - b. in a COMPLETELY OPEN ENDED manner as defined by the term "homologous series" (e.g. see specification page 5) which incorporates ONE OR MORE variations in "substituents" or internal monomer core structure.
 - c. Additionally, the co-polymer and polymer libraries can be "further modified" by "chemical reactions or crosslinking" (e.g. see claims 9 and 27) without indication as to what types of "chemical reactions" and/or "crosslinking" is encompassed.

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Accordingly, the nature of the invention cannot be determined in light of the foregoing and without knowing the exact components, polymeric or monomeric, catalytic, etc. materials that form the copolymer product library (or array) or are used and/or tested in the corresponding process of the instant invention; thus, the claimed invention encompasses an untold number of different compounds of different structure.

In support of the claimed scope of A-B libraries, the examples in the specification teach a copolymer array (or library) product of polyacrylate (specifically polyarylates) copolymers and methods for the syntheses of said polyacrylate copolymers prepared by the condensation of specific monomeric units, i.e. tyrosine-derived diphenol compounds and dicarboxylic acids. E.g. see specification page 6, lines 14-29 to page 7, lines 1-29; page 12, lines 16-31 to page 22, lines 1-28; and Example section on page 24, lines 27-31 to page 38, lines 1-14, to yield positive or negative results. The inventor provides no guidance beyond the copolymer library product of polyacrylate copolymers and methods for the synthesis of said polyacrylate copolymers prepared by condensation of a tyrosine-derived diphenol compound and a dicarboxylic acid. With regard to designing core monomer structure which will predictably result in potentially useful library compounds, there is a complete lack of specification guidance outside of the specifically disclosed embodiments. The specification merely makes vague assertions (e.g. see specification page 5) as to the need for one "To obtain a library of polymers where selected end-use properties change in a predictable and systematic fashion"

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With regard to the description requirement, Applicants' attention is directed to The Court of Appeals for the Federal Circuit which held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398, 1405 (1997), quoting *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original)[The claims at issue in *University of California v. Eli Lilly* defined the invention by function of the claimed DNA (encoding insulin)].

Although directed to DNA compounds, this holding would be deemed to be applicable to a generic of compounds; which requires a representative sample of compounds and/or a showing of sufficient identifying characteristics; to demonstrate possession of the compound or generic(s). For example, in a recent court case in line with *Eli Lilly*, Judge Lourie writing for the CAFC made the following observation:

"A description of an anti-inflammatory steroid, i.e., a steroid (a generic structural term) having the function of lessening inflammation of tissues, fails to distinguish any steroid from others having the same activity or function. Similarly, the expression "an antibiotic penicillin" fails to distinguish a particular penicillin molecule from others possessing the same activity. "

See: J. Lourie decision in *Enzo Biochem, Inc. v. Gen-Probe Inc. et al.* No. 01-1230 (CAFC: Decided April 2, 2002) (citation forthcoming).

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In this regard, applicant is referred to the seminal case of *University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997) and the "Guidelines for Examination of Patent Applications Under the 35 USC 112, first paragraph, 'Written Description' Requirement" published in 1242 OG 168-178 (January 30, 2001).

It is noted that written description is legally distinct from enablement: "Although the two concepts of are entwined, they are distinct and each is evaluated under separate legal criteria. The written description requirement, a question of fact, ensures the that the inventor conveys to others that he or she had possession of the claimed invention; whereas, the enablement requirement, a question of law, ensures that the inventor conveys to others how to make and use the claimed invention." See 1242 OG 169 (January 30, 2001) citing *University of California v. Eli Lilly & Co.*

As pointed out above, the specification discloses only limited examples that are neither representative of the claimed A-B copolymer libraries; nor do the examples represent a substantial portion of the claimed genus sufficient to satisfy the description requirement.

10. Claims 1-3, 5, 9, 10, 14, 17-18, 20, 21, 23, 24, 26 and 27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a copolymer array of polyacrylate copolymers and methods for the syntheses of said polyacrylate copolymers prepared by the condensation of a tyrosine-derived diphenol compounds and dicarboxylic acids, the specification, does not reasonably provide enablement for all copolymer arrays comprising a

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plurality of all copolymers polymerized from two independent variable sets of all compound monomers as made.. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

There are many factors to consider when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any experimentation is "undue". These factors include, but are not limited to:

- a. The breadth of the claims.
 - b. The nature of the invention
 - c. The state of the prior art;
 - d. The level of one of ordinary skill
-
- e. The level of predictability in the art;
 - f. The amount of direction provided by the inventor;
 - g. The presence or absence of working examples;
 - h. The quantity of experimentation necessary needed to make or use the invention based on the disclosure;

See :*In re Wands* USPQ 2d 1400 (CAFC 1988):

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(1-2) *The breadth of the claims and the nature of the invention:*

In the present case, the claims are drawn to a product-by-process claims wherein the product is drawn to a library of "strictly alternating A-B type copolymers" comprising "a number of homologously bivariant copolymers sufficient to incrementally establish quantitative structure-property correlations" which is formed from parallel polymerization of monomers. The CLAIMED scope of copolymer (e.g. A-B) libraries lacks metes and bounds as to the resulting polymer compound (CORE) structure; since :

- a. each of the individual monomers (e.g. A,B) is varied (one or more times) as to monomer "core" structure (e.g. keeping constant the "polymerizable functional groups"),
- b. in a COMPLETELY OPEN ENDED manner as defined by the term "homologous series" (e.g. see specification page 5) which incorporates ONE OR MORE variations in "substituents" or internal monomer core structure.
- c. Additionally, the co-polymer and polymer libraries can be "further modified" by "chemical reactions or crosslinking" (e.g. see claims 9 and 27) without indication as to what types of "chemical reactions" and/or "crosslinking" is encompassed.

Thus the nature of the invention cannot be determined in light of the foregoing and without knowing the exact components, polymeric or monomeric, catalytic, etc. materials that form the copolymer product library (or array) or are used and/or tested in the corresponding process of the instant invention.

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(3 and 5) *The state of the prior art and the level of predictability in the art:*

The state of the prior art is such that the level of predictability in the art cannot be predicted with any certainty as to what specific components, polymeric, monomeric, catalytic, etc. materials that form the copolymer product library or are used and/or tested in the corresponding process and are likely to provide productive results beyond those methods taught in the specification. The inventor provides no guidance beyond the copolymer library product of polyacrylate copolymers and methods for the synthesis of said polyacrylate copolymers prepared by condensation of a tyrosine-derived diphenol compound and a dicarboxylic acid. As a result, one of ordinary skill in the art could not predict what other specific components, polymeric or monomer, catalytic etc. materials that form the copolymer product library or are used and/or tested in the corresponding process in the claimed invention.

To the extent that the presently claimed invention necessitates *critical (e.g. essential)* A-B core (and variables if present) structure specifically claimed in order to achieve recited functional/intended use claim limitations: e.g.

A. "... sufficient to incrementally establish quantitative structure property correlations ...";

B. "... said homologous variations ... are selected to be complimentary ... a different influence on polymer properties ... said second monomer series..." or to "permit the same polymerization conditions to be employed ... in a way that results in all polymers being of sufficiently high molecular weight and similar dispersity "

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applicant must incorporate the necessary chemical structure in the claims in order to render the claimed invention enabling. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (critical method parameters) (CCPA 1976); and *Ex Parte Bhide* (Bd Pat. App. & Int.) 42 USPQ2d 1441 (critical compound structure); see present specification pages 10, 22 and 23.

(4) *The level of one of ordinary skill in the art:*

The level of skill would be high, most likely at the Ph.D. level.

(6-7) *The amount of direction provided by the inventor and the existence of working examples.*

The examples in the specification teach a copolymer array (or library) product of polyacrylate copolymers and methods for the syntheses of said polyacrylate copolymers prepared by the condensation of specific monomeric units, i.e. tyrosine-derived diphenol compounds and dicarboxylic acids. E.g. see specification page 6, lines 14-29 to page 7, lines 1-29; page 12, lines 16-31 to page 22, lines 1-28; and Example section on page 24, lines 27-31 to page 38, lines 1-14, to yield positive or negative results. The inventor provides no guidance beyond the copolymer library product of polyacrylate copolymers and methods for the synthesis of said polyacrylate copolymers prepared by condensation of a tyrosine-derived diphenol compound and a dicarboxylic acid. With regard to designing core monomer structure which will predictably result in potentially useful library compounds, there is a complete lack of specification guidance outside of the specifically disclosed embodiments. The specification merely makes vague

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assertions (e.g. see specification page 5) as to the need for one "To obtain a library of polymers where selected end-use properties change in a predictable and systematic fashion"

- (8) *The quantity of experimentation needed to make or use the invention based on the content of the disclosure:*

While the existence of working examples are limited to Example Section (e.g. page 24 to page 38) the claimed invention encompasses the making and testing of a library of "strictly alternating A-B type copolymers" comprising "a number of homologously bivariant copolymers sufficient to incrementally establish quantitative structure-property correlations" which is formed from parallel polymerization of monomers; which is considerably broader than the exemplified embodiment. However, in light of the complete lack of any guidance as to BOTH the requisite monomer core structure and the resulting utility, it is clear in the present case that specifically disclosed embodiments are not "commensurate" in scope to claims which encompass polymer and copolymer libraries which are totally nondescriptive as to the resulting core structure and/or resulting properties; accordingly, requiring undue experimentation for one of ordinary skill in the art wishing to practice (make/use) the presently claimed invention..

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 1-3, 5, 9, 10, 14, 17-18, 20, 21, 23, 24, 26 and 27 are rejected under 35 U.S.C. 102(a) as being anticipated or in the alternative as obvious over Brocchini et al. JACS Vol. 119 (5/14/97) pages 4553-4554.

Present claims 1-3, 5, 9, 10, 14, 17-18, 20, 21, 23, 24, 26 and 27 are drawn to "product by process claims" which define the product by its method of making. See MPEP 2113 directed to

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“ Product by Process Claims “ . Even though product - by process claims are limited by and defined by the process, determination of patentability is *based on the product itself*. The patentability of a product does not depend on its method of production. If the product in the product - by - process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe* , 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). Once the Examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. *In re Marosi*, 218 USPQ 289, 292 (Fed. Cir. 1983). When the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product - by - process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." *In re Brown* , 173 USPQ 685, 688 (CCPA 1972).

In the present case, the product is drawn to a library of “strictly alternating A-B type copolymers” comprising “ a number of homologously bivariant copolymers sufficient to incrementally establish quantitative structure-property correlations” which is formed from parallel

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polymerization of monomers. In a specific embodiment (e.g. claims 20, 21, 23, 24 and 26) the copolymer library is formed by polymerizing:

a. 1st monomer of a homologous varying monomers with polymerizable hydroxyl groups:
with a

b. 2nd monomer of a homologous varying monomers with polymerizable carboxylic groups.

wherein the 1st monomer is preferably a diphenol and the 2nd monomer is a dicarboxylic acid resulting in a library of polyarylates.

Brocchini et al. teach a library of 112 polyarylates (structure 3) derived from 14 “homologous” (e.g. differing by $-\text{CH}_2-$) tyrosine diphenols (structure 1 as the “1st monomer”) and eight “homologous” (e.g. differing by $-\text{CH}_2-$) diacids (structure 2 as the “2nd monomer”). See. E.g. Fig. 1. The structure 3 library comprises “a number of homologously bivariant

copolymers sufficient to incrementally establish quantitative structure-property correlations” as illustrated by screening of the library by polymer glass transition temperatures as a function of the diacids present. See e.g. Fig. 2. Thus, the reference teaches “the making of ‘strictly alternating’ A-B type copolymers in which:

a. the 1st monomer contains a reactive group for attachment of a series of ‘pendent chains’ (e.g. “R” variable); and

b. the 2nd monomer allows for systematic variations in the polymer backbone structure” (e.g. the “Y” variable); (e.g. the “homologous variations of said 1st and 2nd monomer series ... have a different influence on polymer properties ...” and

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"since all polymers were derived from very similar monomers, they could be prepared under identical reaction conditions ... ". See page 4553, especially left column.

Thus the reference library is clearly within the scope of the presently claimed invention which renders properties (not explicitly taught by the reference) of such compounds presently recited inherent (e.g. "sufficiently high molecular weight"; "similar polydispersity" etc) with intended use limitations (e.g. in compound/composition claims) not being afforded patentable weight (e.g. "incrementally establish quantitative structure property correlations").

14. Claims 1-3, 5, 9, 10, 14, 17-18, 20, 21, 23, 24, 26 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by, or in the alternative as obvious over Fiordeliso et al. J.Biomater. Sci. Polym Edn. Vol. 5, No. 6 pages 497-510 (1994) alone, or if necessary, further in view of Brocchini et al. JACS (5/14/97) pages 4553-4554 for demonstrating INHERENCY. .

Present claims 1-3, 5, 9, 10, 14, 17-18, 20, 21, 23, 24, 26 and 27 are drawn to "product by process claims" which define the product by its method of making. See MPEP 2113 directed to "Product by Process Claims ". Even though product - by process claims are limited by and defined by the process, determination of patentability is *based on the product itself*. The patentability of a product does not depend on its method of production. If the product in the product - by - process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe* , 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). Once the Examiner provides a rationale

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tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. *In re Marosi*, 218 USPQ 289, 292 (Fed. Cir. 1983). When the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product - by - process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." *In re Brown*, 173 USPQ 685, 688 (CCPA 1972).

In the present case, the product is drawn to a library of "strictly alternating A-B type copolymers" comprising "a number of homologously bivariant copolymers sufficient to incrementally establish quantitative structure-property correlations" which is formed from parallel polymerization of monomers. In a specific embodiment (e.g. claims 20, 21, 23, 24 and 26) the copolymer library is formed by polymerizing:

- a. 1st monomer of a homologous varying monomers with polymerizable hydroxyl groups:
with a
 - b. 2nd monomer of a homologous varying monomers with polymerizable carboxylic groups.
- wherein the 1st monomer is preferably a diphenol and the 2nd monomer is a dicarboxylic acid resulting in a library of polyarylates.

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Fiordeliso et al. teach a library of five *separately (co) polymerized* (E.g. condensed, in liquid solution) polyarylates which were synthesized from “homologous” “diacid” monomer component and a “homologous” diphenol monomer components (e.g. see Figures 1 and 2). It is noted that the reference teaching of a “*library*” (e.g. a collection) of five distinct polyarylates copolymers regardless of the means of syntheses (separately or otherwise) meets the presently claimed product-by-process claims since this type of claim is viewed by the PTO as a product claim. In any event the reference does teach the use of method steps within the scope of the presently claimed invention. Further, the reference teaches that the polyarylates can be “further modified” by “chemical reactions” since the polymers “degraded” (e.g. underwent a “chemical reaction”) under physiological conditions (e.g. see Abstract); thus meeting present claims 9 & 27.

Additionally, the Fiordeliso et al. Reference suggests the syntheses of larger libraries including:

- a. Different diphenols components having pendent chains of ethyl to octyl (e.g. y is 2-8); and
- b. Different diacid components having 2-8 flexible -CH₂- units in the diacid polymer backbone.

E.g. See page 499 figure 2 and first full paragraph.

Accordingly, the Fiordello reference discloses and suggest polyarylate libraries of from 5 to 49 or more (e.g. 7 (diphenols)x7(diacids)) derived from “homologous”(e.g. differing by -CH₂-) tyrosine diphenols and “homologous” (e.g. differing by -CH₂-) diacids which would represent a “number of homologously bivalent copolymers sufficient to incrementally establish quantitative structure-property correlations” since the present claims are not limited to a library number of

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compounds and additionally as illustrated by the screening of the Fiordello library compounds for various properties e.g. polymer glass transition temperatures; dye release etc. Additionally, the Fiordello reference INHERENTLY teaches “the making of ‘strictly alternating’ A-B type copolymers within the scope of the presently claimed invention since the Fiordello reference teaches : polymerizing

- a. the 1st monomer contains a reactive group for attachment of a series of ‘pendent chains’ (e.g. “R” variable); and
- b. the 2nd monomer allows for systematic variations in the polymer backbone structure” (e.g. the “Y” variable); (e.g. the “homologous variations of said 1st and 2nd monomer series ... have a different influence on polymer properties ...” and

“since all polymers were derived from very similar monomers, they could be prepared under identical reaction conditions ... “. See page Brocchin et al. at 4553, especially left column.

Thus the reference library is clearly within the scope of the presently claimed invention which renders properties (not explicitly taught by the reference) of such compounds presently recited inherent (e.g. “sufficiently high molecular weight”; “similar polydispersity” etc) with intended use limitations (e.g. in compound/composition claims) not being afforded patentable weight (e.g. “incrementally establish quantitative structure property correlations”).

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15. Claims 1-3, 5, 9, 10, 14, 17-18, 20, 21, 23, 24, 26 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by, or in the alternative as obvious over Kohn et al. US Pat. No. 5,216,115 (6/93).

Present claims 1-3, 5, 9, 10, 14, 17-18, 20, 21, 23, 24, 26 and 27 are drawn to "product by process claims" which define the product by its method of making. See MPEP 2113 directed to "Product by Process Claims". Even though product - by process claims are limited by and defined by the process, determination of patentability is *based on the product itself*. The patentability of a product does not depend on its method of production. If the product in the product - by - process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). Once the Examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. *In re Marosi*, 218 USPQ 289, 292 (Fed. Cir. 1983). When the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product - by - process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then

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obtain prior art products and make physical comparisons therewith." *In re Brown*, 173 USPQ 685, 688 (CCPA 1972).

In the present case, the product is drawn to a library of "strictly alternating A-B type copolymers" comprising "a number of homologously bivariant copolymers sufficient to incrementally establish quantitative structure-property correlations" which is formed from parallel polymerization of monomers. In a specific embodiment (e.g. claims 20, 21, 23, 24 and 26) the copolymer library is formed by polymerizing:

- a. 1st monomer of a homologous varying monomers with polymerizable hydroxyl groups:
with a
- b. 2nd monomer of a homologous varying monomers with polymerizable carboxylic groups.
wherein the 1st monomer is preferably a diphenol and the 2nd monomer is a dicarboxylic acid

resulting in a library of polyarylates.

Kohn et al. teaches a collection (e.g. library) of aliphatic/aromatic polyarylates having repeating structural units (e.g. see col. 4 and formula 1) which represents a collection of "strictly alternating A-B type copolymers" within the scope of the presently claimed invention. The copolymers represent "a number of homologously bivariant copolymers" within the scope of the presently claimed invention (e.g. see col. 4-5: formula I where X is H; Y is a pendent group; and R is as defined in column 5, including unsubstituted alkyl) which contain a varying monomer backbone (e.g. R variable of dicarboxylic acid) and a varying substituent group (e.g. the Y pendent group of the dihydroxy tyrosine derived monomer). Thus the reference library is clearly

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within the scope of the presently claimed invention which renders properties of such compounds presently recited inherent (e.g. "sufficiently high molecular weight"; "similar polydispersity" etc) with intended use limitations (e.g. in compound/composition claims) not being afforded patentable weight (e.g. "incrementally establish quantitative structure property correlations"). In any event it is further noted that the Kohn reference teaches methods of syntheses, library compound molecular weights and screening of the compound libraries for "quantitative structure property correlations" which are within the scope of the presently claimed invention e.g. see examples; particularly examples and col. 12-13.

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16. Claims 1-3, 5, 9-10, 14, 17-18, 20-21, 23-24 and 26-27 are rejected under 35 USC 103 for obviousness over Kohn 5,216,115, Gordon et al., J.Med. Chem. Vol. 37 No.10 pages 1385-1401 and Still et al. US 5,565,324.

17. Claims 1-3, 5, 9-10, 14, 17-21, 24 and 27 are rejected under 35 USC 103 for obviousness over Kohn 4,980,449, Gordon et al., J.Med. Chem. Vol. 37 No.10 pages 1385-1401 and Still et al. US 5,565,324.

Discussion

Applicant's arguments directed to the above obviousness rejection were considered but deemed nonpersuasive for the following reasons.

Initially, it is noted that the substance of the above obviousness rejections as recited in the prior office action are hereby incorporated by reference in their entirety. Additionally, in response to applicant's newly amended claims, it is further noted that both of the above rejections are further modified to incorporate the following:

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It is noted that the Still '324 reference teaches that combinatorial syntheses can be performed, at the option of the practitioner, as a matter of design choice, in either the same vessel or in different vessels (e.g. separate syntheses e.g. an array format): "In carrying out the syntheses ... One can use microtiter well plates, individual containers, columns, gels, Terasaki plates, flasks, Merifield syntheses vessels, etc. (E.g. see col. 15, lines 7-20: see also col. 15, lines 32-col. 16, line 21). Accordingly, making the library in one vessel or in separate vessels is an obvious design choice to one of ordinary skill in the art at the time of applicant's invention.

In response to the above obviousness rejections applicant argues that the Gordon et al. and/or Still et al. references "teach away" from the presently claimed invention. In this respect, applicant first argues that the Gordon et al. reference "discloses the single pot synthesis of small molecules employing building blocks of approximately 150 dalton molecular weight ... which represents the classic approach to the combinatorial synthesis of small compounds in a single vessel to create libraries to be analyzed by simple biological procedures to fish out lead compounds from the many species present in such single pot libraries".

This argument is not convincing for several reasons.

First, even if applicant's argument were agreed upon by the Examiner (which it is not), applicant has overlooked the fact that the claims are drawn to a product-by-process claims. Accordingly, the Examiner would argue that a single pot process would result in "A copolymer library of different copolymers" within the scope of the presently claimed invention, irrespective

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of whether the syntheses occurred in a single vessel or different vessels since the references (e.g. the Kohn patent references) polymerize monomer units within the scope of the presently claimed invention.

Secondly, applicant's interpretation of the Gordon et al. reference appears to be misguided in several respects. The Gordon et al. reference, taken as a whole, suggests the applicability of "Combinatorial Technologies" to drug discovery without limitation of the strategy employed. The Examiner has not been able to locate a Gordon reference teaching that suggests only the use of a "single vessel" combinatorial syntheses to the exclusion of the parallel techniques. In fact the Gordon et al. reference appears to strongly *teach toward* performing parallel/simultaneous array (e.g. separate reaction vessels) syntheses. E.g. see pages 1391-1393 (e.g. page 1392, left column, first line e.g. "on a solid support in an **array format**"). Additionally, the author's biography (on the first page of the article, left column) describes one of the authors as "Stephen P.A. Fodor" who together with his colleagues "led the development of new technologies, *merging photolithography with combinatorial solid-phase chemistry*. As recognized by those of ordinary skill in the art, the Fodor et al. (E.g. from Affymetrix) photolithography/solid phase chemistry technique is a parallel syntheses technique **in an array format**.

Thirdly, in response to applicant's arguments against the Gordon et al. reference individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

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In this respect, the Still reference teaches that combinatorial syntheses can be performed, as a matter of design choice, in either one vessel , or separate vessels (e.g. array format).

Turning to the Still et al. reference, applicant argues that “Still et al. excludes polymers ... but instead is directed to “oligomers and synthetic non-repetitive organic molecules”.

Applicant’s interpretation of the Still et al. reference teaching is misguided since the Abstract clearly teaches that the Still et al. combinatorial method addresses “synthetic schemes” in which “*Various products* can be produced” ... *such as* oligomers and synthetic non-repetitive organic molecules. E.g see Still et al. Abstract.

Accordingly, applicant’s argument is misguided since the Still et al. combinatorial scheme addresses “Various products” and thus is not limited to any particular structure. Further, it would appear that the term “oligomer” would encompass the condensation of different monomer units as in the presently claimed invention. Thirdly, in response to applicant's arguments against the Still et al. reference individually, it is again noted that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this respect it is again further noted that the Still reference applies to the combinatorial syntheses of “Various products” in general, including oligomers, which should encompass combinatorial syntheses of polymers (e.g. via monomeric units) as presently claimed. Additionally, the Still reference teaches that combinatorial syntheses can be performed, as a matter of design choice, in either one vessel , or separate vessels (e.g. array format).

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Applicant in the future is encouraged to more specifically cite the portion of the article being referred to in argument(s) presented to the Examiner in order to facilitate the ability of the Examiner to address his/her concerns.

Thus, the above obviousness rejections, as modified, is hereby retained.

General information regarding further correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Celsa whose telephone number is (703) 305-7556.

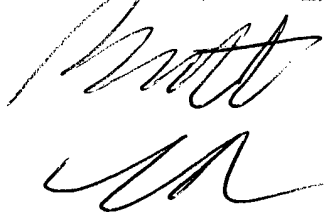
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang (art unit 1639), can be reached at (703)306-3217.

Any inquiry of a general nature, or relating to the status of this application, should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Bennett Celsa (art unit 1639)

April 1, 2003

BENNETT CELSA
PRIMARY EXAMINER

Handwritten signature of Bennett Celsa, consisting of a stylized 'B' and 'C'.